



State of Louisiana
DEPARTMENT OF ENVIRONMENTAL QUALITY
OFFICE OF ENVIRONMENTAL COMPLIANCE

April 27, 2010

The Honorable Edward J. Markey, Chairman
Subcommittee on Energy and Environment
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515-6155

Dear Chairman Markey:

On behalf of the State of Louisiana we would like to take this opportunity to respond to your request for information dated March 18, 2010. That letter requested information regarding Louisiana's oversight of medical patients being treated and released with medical isotopes. Our radiation regulations can be found on our website at <http://www.deq.louisiana.gov/portal/tabid/1674/Default.aspx#ERC>.

Q1. How many I-131 facilities are overseen by your State?

Response 1

Louisiana licenses 81 such facilities.

Q2. How often does your state perform sampling inspections at each of these I-131 licensee facilities?

Response 2

Louisiana inspects its medical licensees that administer therapeutic doses of 1-131 every one to three years. Inspection frequencies are based upon the type and scope of the program, which are usually more frequent than the NRC's. Our Broad Scope Medical licensees are inspected annually. Typically, large medical institutions and university-run medical facilities hold Medical Institution Broad Scope licenses. The medical licensees that administer therapeutic doses of 1-131, referred to as a Medical Institution - Written Directive Required, require an inspection frequency of once every three years.

Q3. What does such an inspection entail?

Response 3

Louisiana follows all NRC applicable guidance outlined in Inspection Manual Chapter 2800 (IMC 2800), this includes the inspection criteria for a facility requiring written directives, including those facilities that administer 1-131, in Inspection Procedure (IP) 87131 "Nuclear Medicine Programs, Written Directive Required". We have developed our own similar procedure which each inspector uses as a guide. With respect to the release of patients, IP 87131 requires, in part, that

the inspector determine by direct observations and, if needed, review of selected records that the licensee is knowledgeable about patient release criteria and is in compliance with the Louisiana patient release criteria.. Inspectors also verify that the licensee's evaluation for release of the patient meets the regulatory requirements. The inspectors review a sample of the licensee's written instructions to the patient to determine if the instructions meet current requirements.

Q4. NCRP 155 includes "Radiation Safety Precautions for Radiopharmaceutical Therapy Patients." For a patient receiving 175 millicuries of I-131, the patient is instructed not to hold or embrace children for more than 10 minutes a day for 21 days; to refrain from sharing a bed with one's sleeping partner for 7 days; and for the first day, to store an launder one's used clothing and bed linens separately from the rest of the household, using two rinse cycles; to wipe down the telephone with paper towels and then discard the paper towels; etc. What instructions has you State given to its medical licensees about how to provide guidance to patients to ensure that these radiation precautions will be followed.

Response 4

Louisiana recommends that NUREG 1556 Vol. 9 be referenced for appropriate procedures.

Q5. In the past 10 years how many times has your State, as part of these inspections, requested documentation from the licensee detailing the individual analysis and/or dose calculations used when determining whether to send a patient that was treated with I-131 in excess of the default limits home, or to a hotel?

Response 5

Inspectors review the licensee's operating procedures to verify compliance with the release criteria. Their documentation is reviewed at that time. We do not require copies of those documents.

Q6. In the past 10 years how many times has your State as part of these inspections, requested documentation from the licensee facilities that details the guidance provided to the patient by the licensee facility when the patient is released from licensee care?

Response 6

During his inspection, the inspector reviews a sample of the relevant documents and records supporting the patient's release. We do not maintain copies of these records.

Q7. In the past ten years how many times has your State identified problems with the individualized analysis and/or dose calculations used or guidance provided to the patient by the licensee facility?

Response 7

In the past 10 years Louisiana has not identified any such problems.

Q8 In situations where an individualized analysis of dose to others is required, it would seem impossible for the authorizing physician to do so for a patient going to a hotel, since this would require a knowledge of the layout of the

hotel and the proximity to the nearest other guest, who might be a child or a pregnant woman sleeping on the other side of a wall. Do you agree?

Response 8

Louisiana licensees have demonstrated that they are quite capable of calculating dose estimates using reasonable assumptions concerning occupancy, building geometry and other factors. We believe that a licensee is capable of calculating conservative dose estimates using reasonable assumptions concerning occupancy, building geometry, and other factors. In all outpatient cases, one can not possibly control what the patient does when they leave the licensed facility.

Q9 Has your State ever attempted to determine how many patients treated with I-131 are a) sent home, b) sent to a hotel or c) kept in the hospital for additional time?

Response 9

Inspectors evaluate and review the circumstances under which patients treated with I-131 are released. We do not keep records of how many patients are released to various locations.

Q10 In patients with doses in excess of the default limits, has your State ever attempted to determine whether these I-131 licensee facilities always perform individualized analysis of each patient's living circumstances prior to releasing them? If not, why not? If so, has your state ever encountered situations when individual analyses and/or dose calculations were not performed when they were required?

Response 10

Inspectors review and evaluate analyses and/or dose calculations. To date, we have not encountered any situations when those calculations were not performed.

Q11 What are the disclosure rules for patients who go to a hotel following treatment? Are licensees required to give patients explicit instructions to provide to hotel management?

Response 11

Louisiana refers licensees to the guidance document NUREG-1556, Volume 9, Revision 2, for guidance in how to meet this performance-based objective.

Q12 Has your State ever issued an advisory or guidance warning licensees not to send radioactive patients to hotels? If so, please provide copies.

Response 12

Louisiana refers the licensees to NUREG 1556, Vol. 9, Revision 2, "Program Specific Guidance about Medical Use Licensees.

Q13 Are your licensees required to report to you instances in which released I-131 patients caused radiation exposure to family members or members of the public?

Response 13

Licensees calculate those exposures and provide instructions to the patients. Our inspectors review those licensee records at the required inspection intervals. To date, no such exposures have been noted.

Q14 Please provide copies of all correspondence, including emails, letters, meeting or telephone notes or other materials between your State and the NRC related to the release of patients that have been treated with radionuclides.

Response 14

The only records of this type kept by Louisiana can be found in the NRC IMPEP program reviews. Those are listed on the NRC website.

Q15 Please provide reports for instances in which documents relating to patient release were found to be missing, inadequate, or unclear during the course of a sampling inspection. If your sampling inspections found that a licensee knew of a patient who went to a hotel after treatment, whether or not by explicit instruction, please provide all documentation relating to those cases.

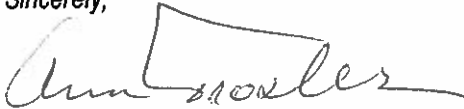
Response 15


Inspections have found no instances of missing documents of this kind. If the inspector had found an unclear record he would have asked for clarification and/or cited it as a violation. No records of those findings have been found to date.

Please note that the Louisiana Department of Environmental Quality Radiation program has been found to be adequate and compatible with our Nuclear Regulatory Commission agreed upon regulatory delegation. Our Integrated Materials Performance Evaluation Program (IMPEP) reviews can be found on the NRC website at: <http://nrc-stp.ornl.gov/reviews.html#LA>.

If you need additional information or further clarification, please do not hesitate to contact me at 225-219-3624, email Jeff.Meyers@la.gov, or Ann Troxler at 225-219-3991, email at ann.troxler@la.gov.

Sincerely,



Jeffrey P. Meyers, 
Administrator
Emergency and Radiation Services Division

Cc: Peggy Hatch, Secretary
Louisiana Department of Environmental Quality